Remarks

After amendment, claims 1, 3-8, 10-20, 25 and 27-36 remain pending in the present applications. Claims 2, 9 and 26 are cancelled in this amendment in order to expedite allowance of the presently pending claims, which are directed to compositions which contain three specific components which have a requirement for certain weight ratios of those components. The compositions according to the present invention (claims 1 and 3-7) relate to a mixture of three specific components which together, when used in the claimed weight ratios are useful for producing storage stable emulsions containing high concentrations of water (i.e. 50% to 90% water). Note that claim 1 has been amended to reflect that the three component mixture is useful for formulating storage stable high water content water-in-oil emulsions. The independent claims now recite the inclusion of dibehenyl fumarate, PEG 1500 dihydroxystearate and stearic monoethanolamide in particular weight ratios which can be used to provide storage stable water-in-oil emulsions. Support for the amendments to the claims may be found in the specification at page 11, in the first few lines of the first full paragraph (support for the amount of the emollient oil in the compositions according to the present invention), at page 13, line 4 (support for at least 60% by weight water) and throughout the originally filed specification, including the claims. The combination of claimed components in the claimed weight ratios for providing storage stable, high water content water-in-oil emulsions is clearly novel and non-obvious over the art cited by the Examiner. It is respectfully submitted that the claims are in condition for allowance and such action is earnestly solicited.

The courtesy of the telephonic interview with Examiner Hui on May 20, 2004 is respectfully acknowledged.

The Examiner has rejected pending claims 1-36 under 35 U.S.C. §103. For the reasons which are set forth in detail hereinbelow, Applicants respectfully submit that the amended claims presented in the instant paper address the Examiner's concerns and are thus in condition for

allowance.

The §103 Rejection

The Examiner has rejected claims 1-36 as being un patentable over Fogel, U.S. patent number 6,126,949 ("Fogel"), Herstein, U.S. patent number 5,902,591 ("Herstein") and McCutcheon's Emulsifiers & Detergents North American Edition, 2000, page 18 ("McCutcheon") under 35 U.S.C.§103 for the reasons stated in the office action.

The Examiner cites Fogel for teaching component A, a dialkyl fumarate, especially dibehenyl fumarate to be useful to harden or stiffen an oil-in-water or water-in-oil emulsion and to enhance stability of water-in-oil emulsions. Fogel also is cited for teaching emollients to be used with dibehenyl fumarate as petrolatum, mineral oil, various vegetable oils and neopentanoates such as octyl dodecyl neopentanoate and that the water-in-oil emulsion may contain varying amounts of water. Fogel is cited for also teaching the use of nonionic emulsifiers in water-in-oil emulsions.

Herstein is cited for teaching that a 5-10% vitamin C containing topical cosmetic composition employing several preferred emulsifiers, one of which is stearic monoethanolamide (component C). McCutcheon is cited generically for teaching the use of Arlacel P135 in cosmetics.

The Examiner readily admits that the references do not expressly teach that the three components as claimed can be incorporated into a single composition. The Examiner also readily admits that the three references do not expressly teach the three components within the claimed weight ratios. This admission should end the issue as to whether or not the claims are patentable. Nonetheless, the Examiner maintains his argument that it would have been obvious to incorporate the three components into a single composition as an emulsion within the claimed

weight ratio. Applicant respectfully maintains his strong disagreement. Applicants respectfully submit that the Examiner has not made out a cogent case of *prima facie* obviousness, let alone a cogent case of obviousness.

The present invention is directed to the unexpected discovery that the inclusion of a three component mixture of three specific compounds: dibehenyl fumarate, PEG 1500 dihydroxystearate and stearic monoethanolamide *together, within the claimed weight ratios,* are useful for producing storage stable high water content emulsions (about 50% to 90% by weight water). The present invention is directed to compositions which may be used to manufacture storage stable, high water content emulsions (claims 1 and 3-7), emulsion compositions (claims 8 and 9-24) and personal care compositions (claims 25 and 27-36), each of which contains the three component mixture (A, B and C) within the specifically claimed ratios, which are critical to the claimed invention.

The present invention, is directed to a noteworthy advance in the art because the claimed invention may be used to produce high water content storage stable water-in-oil emulsions which significantly lower the cost of producing cosmetics and other personal care products because of the amount of water (a low cost component) contained therein. Thus, the inventor of the present invention has creatively produced a three component mixture, which may be used to create desirable water-in-oil emulsions which are cost effective and storage stable. The present invention represents a patentable advance in the art. Contrary to the Examiner's contention, the cited prior art in no way discloses or suggests the present invention. Not only does the art not suggest the particular weight ratios of the three components A, B and C of the present invention, but the art does not even suggest the specific combination of components.

Note that the emulsion compositions contain substantial amounts of water, which, in combination with other lipophilic components of the present invention, would normally *readily separate* into more than one phase. Applicant, with his invention, has discovered a means to

maintain the emulsion as a stable emulsion, as a storage stable composition. These compositions are commercializable and cost effective. The present invention is clearly *not taught or suggested by the cited prior art.*

Fogel, as indicated by the Examiner, is directed to novel dialkyl fumarate compositions, which are cited for their use in dermatological products. The Examiner readily admits that Fogel does not disclose or suggest components B or C, which must be added to compositions according to the present invention *within the claimed weight ratios* in order to secure the unexpected characteristics of emulsion compositions (i.e., maintaining storage stability in a composition which, because of the components included, would normally readily separate into two or more phases). Although Fogel is a generally useful reference, it cannot be raised to the level of suggesting that it teaches either component B or component C of the present invention *in combination, or the weight ratios of the instant invention as set forth by the claims* which find use for the purpose of increasing the storage stability of high water-containing emulsions. Nor do the other references cited by the Examiner somehow add to Fogel to render the present invention unpatentable.

Herstein is directed to stable topical cosmetic pharmaceutical emulsions of ascorbic acid which comprise ascorbic acid, in combination with an emulsion composition containing a stabilizing effective amount of an organoclay composition. The Herstein compositions include anywhere from about 1% to about 10% by weight of the emulsifier. Of the literally ***thousands*** of disclosed emulsifiers which may be used in Herstein, one is stearic monoethanolamide. Notwithstanding the disclosure of this emulsifier, Herstein teaches that the emulsifier, in order to be effective *must be formulated* **in combination with an organoclay composition**. ***Note that the reason Herstein combines the emulsifier with the organoclay composition is to avoid having the emulsion break down- that is, the organoclay composition functions as a stabilizer for the Herstein disclosed emulsion. See Herstein at column 2, lines 34-62.*** Thus, Herstein provides a solution to emulsifier breakdown- by using an organoclay composition in an emulsion.

In the present invention, Applicant has discovered that the combination of the three components in the claimed weight ratios is the solution to the problem Herstein solved in a totally different way. It is respectfully submitted that Herstein does not provide motivation for the present invention.

It is posited that Herstein does not disclose or even *obliquely* suggest the use of dialkyl fumarates or polyethyleneglycol dihydroxystearate or the weight ratio which is used in the present compositions *because Herstein solved the problem of emulsifier breakdown by adding an effective amount of an organoclay composition*. This is not the present invention and does not bring to mind or motivate the present invention. The dialkyl fumarates of the present invention are not the hydrophilic gelling agents which Herstein suggests can be used to stabilize emulsions. Herstein at column 2, lines 34-62. Indeed, if anything dialkyl fumarate tends to be hydrophobic, relative to hydrophilic gelling agents. The dialkyl fumarates of Fogel are not just different animals than the hydrophilic gelling agents of Hertstein, they are chemical *opposites* (from a physicochemical characteristic perspective). The present invention is particularly inventive in solving the same problem as Herstein by using components which are not even mentioned by Herstein. The components of the present invention are not even related physicochemically to the organoclays or other hydrophilic gelling agentsof Herstein. It is respectfully submitted that Herstein adds nothing to the disclosure of Fogel which would somehow suggest to one of ordinary skill the invention of the present application.

Nor does the disclosure of McCutcheon somehow add to the deficient disclosures of Fogel and Herstein in failing to teach the present invention to one of ordinary skill in the art. McCutcheon is a generic reference which discloses that Arlacel 135 is a polymeric surfactant. Noted here is the fact that McCutcheon simply provides a list of emulsifiers which are commonly available. McCutcheon does not disclose or suggest the present invention. Indeed, McCutcheon does not even disclose that Arlacel 135 is PEG 1500 dihydroxystearate. Rather, McCutcheon simply refers to Arlacel 135 as a polymeric emulsifier available from ICI. It is respectfully

submitted that McCutcheon is barely even relevant to the present invention and only in the sense that it provides a manufacturer for Arlacel 135 and indicates that Arlacel 135 may be used in skin care cosmetics and color cosmetics. Other than that meager disclosure, McCutcheon says nothing else about Arlacel 135.

It is respectfully submitted that the Examiner has not made out a cogent case that the present invention is obvious over the combined disclosures of Fogel, Herstein and McCutcheon. Instead, the Examiner's rejection simply cobbles together unrelated disclosures in the art which happen to be relevant to the present invention *only because of the existence of the present invention.* It is respectfully submitted that the Examiner's rejection is a classic case of ***impermissible hindsight reconstruction***, the likes of which can only be made as a consequence of knowing of the present invention. It is further submitted that the Examiner's rejection is inappropriate.

Applicant respectfully submits that without the information provided in the present specification and the disclosure of the instant invention, one of ordinary skill would not be motivated to even combine these three isolated references, each of which refer to only a single component as claimed. Thus, Fogel may refer to dialkyl fumarate, but in no way discloses either polyethylene glycol dihydroxystearate or the alkyl monoethanolamide emulsifier. Herstein may disclose stearic monoethanolamide as one of numerous emulsifiers to produce stable emulsions, ***but only in combination with an organoclay compound or other hydrophilic gelling agent.*** Herstein does not disclose alkyl fumarate or polyethyleneglycol dihydroxystearate emulsifiers and indeed, if anything, suggests that the present invention won't work because the present invention does not utilize a hydrophilic gelling agent. In this sense, Herstein actually *teaches away* from the present invention. McCutcheon only refers to the manufacturer of PEG 1500 dihydroxystearate, but does not provide any additional useful information. It is therefore fair to say that one of ordinary skill would not have combined the teachings of the three references when there is not even a suggestion that it is desirable to combine these components. Moreover,

when taken with the fact that the present invention requires certain weight ratios of these three components in order to provide the claimed invention which produces unexpected characteristics of the compositioons, it is simply not cogent that the claimed invention is obvious over a combination of the cited references.

It is Respectfully Submitted that Relevant Caselaw Does Not Support the Examiner's Position that the Present Invention Is Obvious

The Examiner has posited the obviousness rejection as being that of a *prima facie* obviousness objection. ***It is not.*** A *prima facie* obviousness rejection is one that is made based upon the clear suggestion from the references which are cited to combine the components which are claimed. It is respectfully submitted that the Examiner's *prima facie* obvious rejection is not even possible, given that Herstein suggests that stable emulsions can only be made by including a hydrophilic gelling agent in the composition. See Herstein, column 1, lines 34-62. In this sense, Herstein actually *teaches away* from the present invention.

Moreover, in the present case, the specific cited references do not make any reference whatsoever to any of the other components used in the present invention and there is absolutely no disclosure in those references of the weight ratios of the components used in the present invention. Even the Examiner readily admits this in the office action. Thus, the Examiner's argument that the present invention is *prima facie* obvious fails on two counts. Yet, despite the absence of any teaching, as readily admitted by the Examiner, the Examiner maintains that the invention is *prima facie* obvious. It is respectfully submitted that the Examiner has not even made out a case that the present invention is obvious, let alone *prima facie* obvious.

Because the combination of references do not make out a cogent *prima facie* obviouness rejection and because a combination of references which includes the teachings of Herstein, requires that one of ordinary skill look to hydrophilic gelling agents to provide stability to emulsions, Applicant respectfully submits that the Examiner has not made out a case that the

present invention is obvious over the combined teachings of Fogel, Herstein and McCutcheon.

Recent caselaw does not support the Examiner's rejection. If the alleged obviousness of a claimed invention is based on a combination of references, there must be a *rigorous* showing of a clear and particular suggestion, teaching, or motivation to combine the references relied upon. *In Re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999). Such evidence may come from the references themselves, the knowledge of those skilled in the art, or from the nature of the problem to be solved. While this showing may come from the prior art, as filtered through the knowledge of one skilled in the art, *Brown and Williamson Tobacco Corp., Inc.* v. *Philip Morris Inc.*, 56 U.S.P.Q. 2d 1456 (Fed. Cir. 2000), it is still subject to the rigorous requirement that the combination not be motivated by impermissible hindsight. *In Re Dembiczak*, supra. Further, there must be a particular showing that one of ordinary skill in the art would have recognized the invention and believed there was a reasonable likelihood of success that the suggested combination of references would work to yield the claimed invention. *Brown and Williamson Tobacco Corp*, supra. In the present case, Applicants respectfully submit that the Examiner has not made out a cogent case for the rejection of the present application.

The Examiner has failed to provide a rigorous showing of a clear and particular suggestion, teaching, or motivation to combine the teachings of Fogel, Herstein and McCutcheon to yield the compositions of the present invention of the pending claims. To the contrary, without any suggestion or motivation in the art, the Examiner has simply cherry picked individual components which make up the present claimed invention and argued that the claimed components (which are not suggested to be combined by the art) are not only taught to be combined, but are taught to be *combined in the specifically claimed weight ratios to afford the unexpected characteristics of the claimed compositions*. Applicants respectfully submit that it is improper as a matter of law to select, modify and combine references, in essence to *cherry-pick* the disclosures, in this manner in the absence of clear evidence supporting the selection, modification, and combination as claimed . *In Re Dembiczak*, supra. Moreover, it is respectfully

submitted that the Examiner has essentially admitted this in the third full paragraph on page 4 of the January 22, 2004 office action.

There is also no basis for the Examiner to characterize the instant invention as reflecting the mere addition or elimination of well-known ingredients, or to suggest that the Applicants have only identified selected well known ranges of ingredients that are merely the result of "optimization". This misapprehends the claimed invention and the law. "[T]he criterion of §103 is not whether the differences from the prior art are 'simple enhancements' [optimizations], but whether it would have been obvious to make the claimed [invention]." *Continental Can Company USA, Inc.* v. *Monsanto Co.*, 20 U.S.P.Q.2d 1746 (Fed. Cir. 1991). There is no lower threshold in establishing obviousness for cosmetic or personal care related inventions; a uniform standard precludes reliance on hindsight in evaluating the patentability of an invention irrespective of complexity. *Panduit Corp.* v. *Dennison Mfg. Co.*, 1 U.S.P.Q. 2d 1593 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987).

In another case in point with the present rejection, in In re Geiger, 23 U.S.P.Q.2d 1276 (Fed. Cir. 1987), the CAFC reviewed an obviousness rejection in which three prior art references disclosed particular components of a scale and corrosion prevention composition. While each of the components of the composition were conventionally employed in the art for treating cooling water systems, the CAFC held that obviousness cannot be established by combining the teachings of the prior art references to produce the claimed composition absent some teaching, suggestion or incentive to do so. At best, one skilled in the art might find it obvious to try various combinations of these agents. However, that is not the standard of 35 U.S.C. §103. Here, the Examiner is combining references which teach specific emulsifiers and there is no teaching, suggestion or incentive for combining the particular components as Applicant has done. Even if the combination were proper, it does not address Applicant's invention which relates to the specific combination of emulsifiers claimed in the specified weight ratios, which give rise to a combination of emulsifiers which can produce high water content storage stable water-in-oil

emulsions.

Quite separately, the claimed invention does represent an unexpected result and a significant advance in the art. Note the desirability of storage stable, high water content water-in-oil emulsions based upon the commercial viability of such an invention. The present inventor has creatively managed to combine three specific compounds in a set weight ratio as claimed, in order to provide storage stable, high water content water-in-oil emulsions containing 50-90% (preferably, at least about 60%) by weight water in compositions which are adapted for use in the cosmetics/personal care art. Applicant has discovered a way to substantially reduce the cost of materials to be used in cosmetics/personal care products which rely on stable water-in-oil emulsions and their favorable characteristics for presentation and commercializability. The Examiner's attention is drawn in this regard to the emulsion prepared in example 2 of the instant specification. That emulsion, which is storage stable, contains *almost 80% by weight water.* To be able to increase the lowest cost component in a composition to a favorable end result is a noteworthy contribution to the art. The present invention is not taught by the art of record, either alone or in any combination and is not rendered obvious either alone or by those combined teachings.

In light of all of the foregoing, it is respectfully maintained that the instant amendments and remarks address all of the grounds for rejection raised by the Examiner. Accordingly, Applicants respectfully maintain that all of the pending claims 1, 3-8, 10-25 and 27-36 should be passed to issue.

It is respectfully submitted that Applicant has effectively addressed the Examiner's rejection of the originally filed claims under §103, and the rejection is respectfully requested to be withdrawn.

For all of the above reasons, Applicant respectfully asserts that the claims set forth in

the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and indication of such allowability is earnestly solicited.

Applicants have cancelled three claims and added no additional claim. No fee is therefore due for the presentation of this amendment. A request for an extension of time and a check for the requisite fees is enclosed.

The Commissioner is authorized to charge any deficiency in fees or to credit any overpayment to deposit account 04-0838. If any additional fee is due or any overpayment has been authorized please charge/credit Deposit Account No. 04-0838.

Respectfully submitted,

Coleman Sudol Sapone, P.C.

June 16, 2004

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Certificate of Mailing

I hereby certify that this correspondence is being sent by First Class Mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231 on June 16, 2004.

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